30(b)(6) Chu Combined Designations

Designation List Report

Chu, Karen **2022-12-16**

Our Designations	01:02:42
Their Designations	00:12:05
TOTAL RUN TIME	**01:14:48**

Documents linked to video:

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KC7 - 30(b)(6) Chu Combined Designations

DESIGNATION	SOURCE	DURATION	ID
5:12 - 5:23	**Chu, Karen 2022-12-16**	00:00:15	KC7.1
	5:12 K A R E N C H U, the Witness herein, 5:13 having first been duly sworn by the 5:14 Notary Public, was examined and testified 5:15 as follows: 5:16 EXAMINATION BY MS. MAZZOCHI: 5:17 Q. Thank you. Good morning, 5:18 Ms. Chu, my name is Deanne Mazzochi. 5:19 Can you please state your full 5:20 name and address for the record. 5:21 A. Yes, Karen Chu, and my home 5:22 address is 73 Richbell Road, White 5:23 Plains, New York 10605.		
11:21 - 12:07	**Chu, Karen 2022-12-16**	00:00:34	KC7.2
	11:21 Q. And then what was your initial 11:22 role and responsibilities at Regeneron? 11:23 A. So when I joined the company I 11:24 joined as a senior clinical trial 11:25 manager. And then as is true, I think, 12:01 for a lot of small companies, in that 12:02 role wore several different hats and had 12:03 a broad range of responsibilities as it 12:04 related to clinical development. And 12:05 over the years moved into more of a 12:06 clinical project management role and then 12:07 finally into my current role.		
12:08 - 13:22	**Chu, Karen 2022-12-16**	00:01:52	KC7.3
	12:08 Q. Okay. And was your initial 12:09 title, what was it, director of 12:10 therapeutic area, project management? 12:11 A. So that was not my first title 12:12 at Regeneron. 12:13 Q. Okay. What was your first 12:14 title? 12:15 A. My recollection is that my 12:16 first title was senior clinical trial 12:17 manager. But the director of therapeutic 12:18 area project management was a promotion 12:19 into a broader clinical project 12:20 management role.		

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DESIGNATION	SOURCE	DURATION	ID
	12:21 Q. And then did you ever have any 12:22 individuals who reported to you in those 12:23 roles? 12:24 A. At the time that I was a 12:25 clinical trial manager I had a group of 13:01 people that reported to me who, who were 13:02 more junior clinical trial managers and 13:03 involved in the operations of the 13:04 clinical trials. 13:05 Q. Okay. How do you differentiate 13:06 what your role was versus what you call 13:07 the operations of the clinical trials? 13:08 A. So within clinical research, 13:09 there are several people who contribute 13:10 to any aspect of conducting a clinical 13:11 trial. So the actual operations of the 13:12 clinical trial, which includes everything 13:13 from ensuring that clinical study sites 13:14 are identified and trained appropriately 13:15 to providing supplies for the clinical 13:16 study sites, to deciding which 13:17 laboratories to use or how labs will be 13:18 collected. That typically is considered 13:19 part of the operations role. So they're 13:20 really, that, you know, they really 13:21 oversee the actual execution of the 13:22 clinical trials.		
14:10 - 14:14	**Chu, Karen 2022-12-16** 14:10 Q. Let's focus on VEGF-Trap. If I 14:11 call VEGF-Trap aflibercept, is that all 14:12 right as well? 14:13 A. That's all right. I understand 14:14 it to be the same molecule.	00:00:11	KC7.4
17:20 - 17:23 D200.1	**Chu, Karen 2022-12-16** 17:20 (Defendant's Exhibit 200, 17:21 Plaintiff's Rule 26(a) Initial 17:22 Disclosures, was so marked for 17:23 identification, as of this date.)	00:00:01	KC7.5
18:06 - 18:08	**Chu, Karen 2022-12-16** 18:06 A. So I can confirm that the	00:00:06	KC7.6

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DESIGNATION	SOURCE	DURATION	ID
	18:07 document says Plaintiff's Rule 26(a) 18:08 Initial Disclosures.		
31:05 - 31:10	**Chu, Karen 2022-12-16**	00:00:17	KC7.7
Clear	31:05 Q. Sure. Again, I'm just trying 31:06 to get at what are identified as alleged 31:07 inventions in Defendant's Exhibit 4, the 31:08 '601 patent. You said that in your role 31:09 you participated in the design of the 31:10 studies, for example.		
31:11 - 31:15	**Chu, Karen 2022-12-16**	00:00:15	KC7.8
	31:11 Can you tell me anything that 31:12 you recall about anything inventive or 31:13 unique, or new or different about those 31:14 particular trials that relate to the 31:15 inventions set forth in the '601 patent?		
31:19 - 32:04	**Chu, Karen 2022-12-16**	00:00:34	KC7.9
	31:19 A. Certainly with every new 31:20 molecule, the properties of the molecule 31:21 as well as considerations around its 31:22 clinical use go into the design of any 31:23 trial. 31:24 And Eylea represented a new 31:25 anti-VEGF treatment that we felt had real 32:01 potential advantages and designed the 32:02 trial in a way that we felt we could 32:03 demonstrate those unique properties to 32:04 the best extent possible.		
34:18 - 34:21	**Chu, Karen 2022-12-16**	00:00:10	KC7.10
	34:18 Q. And is it fair to say that your 34:19 clinical trials were designed to try to 34:20 optimize or maximize the chance of 34:21 success?		
34:24 - 35:01	**Chu, Karen 2022-12-16**	00:00:11	KC7.11
	34:24 A. So I think it's true that in 34:25 clinical development you're always trying 35:01 to maximize your chances of success.		
35:02 - 35:04	**Chu, Karen 2022-12-16**	00:00:09	KC7.12
	35:02 Q. Would Regeneron have followed 35:03 or pursued a clinical trial that it		

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DESIGNATION	SOURCE	DURATION	ID
	35:04 thought it was going to fail?		
35:07 - 35:23	**Chu, Karen 2022-12-16**	00:00:52	KC7.13
	35:07 A. So there is always a risk of 35:08 failure. Clearly, you know, the -- 35:09 especially for Phase III trials, there is 35:10 a statistical threshold that you must 35:11 meet and there's always a chance that you 35:12 would not meet that for various reasons. 35:13 So I don't think it's true that 35:14 Regeneron would not have pursued a trial 35:15 that had a chance of failure. 35:16 Q. Yeah, maybe we can phrase it 35:17 this way. Is it fair to say that in your 35:18 time at Regeneron, if Regeneron was going 35:19 to pursue a clinical trial, they believed 35:20 they would be able to meet that, the 35:21 clinical endpoints they put in place? 35:22 They wouldn't have spent the money on a 35:23 clinical trial if they didn't?		
36:01 - 36:06	**Chu, Karen 2022-12-16**	00:00:14	KC7.14
	36:01 A. So, again, every clinical 36:02 trial, you know, we try to design it for 36:03 success. But there is always a risk that 36:04 a clinical trial would fail for one 36:05 reason or another, whether that's safety 36:06 or efficacy.		
36:07 - 36:10	**Chu, Karen 2022-12-16**	00:00:08	KC7.15
	36:07 Q. Okay. When it comes to 36:08 aflibercept, were there any clinical 36:09 trials you designed that led to failure 36:10 as opposed to success?		
36:13 - 36:14	**Chu, Karen 2022-12-16**	00:00:03	KC7.16
	36:13 Q. With regard to the 36:14 ophthalmology category?		
36:16 - 36:19	**Chu, Karen 2022-12-16**	00:00:14	KC7.17
	36:16 A. Can I ask for some limitations 36:17 on the extent of my answer? Is there a 36:18 time frame that we are referring to? 36:19 Q. Sure, let's say 2006 forward.		

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DESIGNATION	SOURCE	DURATION	ID
36:21 - 37:18	**Chu, Karen 2022-12-16**	00:01:07	KC7.18

36:21 A. So actually, most recently
36:22 Regeneron has reported two clinical
36:23 trials with aflibercept that did not meet
36:24 their primary endpoint.
36:25 Q. And which were those?
37:01 A. Those are trials in the
37:02 treatment of retinopathy of prematurity.
37:03 Q. And what was the dosing regimen
37:04 for those?
37:05 A. It's .4 milligrams either
37:06 unilaterally or bilaterally for up to
37:07 three monthly doses.
37:08 Q. When you say for up to three
37:09 monthly doses, you mean with three
37:10 monthly doses or doses separated by three
37:11 months between them?
37:12 A. Sorry. In retinopathy of
37:13 prematurity physicians treat initially
37:14 with a single dose. If that does not
37:15 regress the retinopathy of prematurity
37:16 sufficiently, they can give a second dose
37:17 a month later and a third dose a month
37:18 later with similar considerations.

39:19 - 40:01	**Chu, Karen 2022-12-16**	00:00:23	KC7.19

39:19 Q. Okay. So besides this
39:20 particular study that Regeneron conducted
39:21 for the -- at the request of the FDA for
39:22 pediatric patients, are there any other
39:23 studies that Regeneron has pursued for
39:24 aflibercept in the eye that have failed
39:25 to meet their clinical endpoints?
40:01 A. Not that I'm aware of.

41:09 - 43:01	**Chu, Karen 2022-12-16**	00:01:42	KC7.20

41:09 Q. Well, let's take a look at a
41:10 document that I will mark -- do you have
41:11 an understanding that you've been
41:12 designated to testify on behalf of
41:13 Regeneron as what's referred to as a Rule
41:14 30(b)(6) witness?

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DESIGNATION	SOURCE		DURATION	ID
	41:15	MS. OBERWETTER: I'm just going		
	41:16	to interpose for a moment. You know,		
	41:17	you all have our position on the		
	41:18	30(b)(6) topics that you sent over,		
	41:19	which are really two things, that the		
	41:20	notice is abusively overbroad and		
	41:21	defective. In our view it's not a		
	41:22	valid 30(b)(6) notice.		
	41:23	It is also the case that we are		
	41:24	trying to get you the information that		
	41:25	you need and that you're entitled to		
	42:01	in this case and this witness is well		
	42:02	equipped to do that. So I don't know		
	42:03	exactly how you're intending to use		
	42:04	the 30(b)(6) topics in this		
	42:05	examination. You obviously have our		
	42:06	objections on those.		
	42:07	So I'll let you proceed. I may		
	42:08	ask for a running objection so that I		
	42:09	do not interfere with your questions.		
	42:10	MS. MAZZOCHI: I understand that		
	42:11	Regeneron has put in the record, in a		
	42:12	letter addressed to Mylan, that they		
	42:13	object in various ways to our 30(b)(6)		
	42:14	deposition topics. But nonetheless,		
	42:15	Regeneron has indicated that Ms. Chu		
	42:16	would be identified as a responsive		
	42:17	witness for various of these topics.		
	42:18	I understand you have an objection to		
	42:19	them generally. Let's try to at least		
	42:20	go through them and see what Ms. Chu		
	42:21	actually has some knowledge and can		
	42:22	testify to.		
	42:23	MS. OBERWETTER: I would say our		
	42:24	position is not exactly as you just		
	42:25	stated. It's as set forth in the		
	43:01	letter that I sent.		
43:20 - 44:01	**Chu, Karen 2022-12-16**		00:00:15	KC7.21
	43:20	Q. All right. Ms. Chu, can you		
D202.1	43:21	just confirm that you have a document		

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DESIGNATION	SOURCE	DURATION	ID
	43:22 before you marked DX 202 that is marked 43:23 Karen Chu, 30(b)(6) deposition topics? 43:24 A. Yes, the title of the document 43:25 is "Karen Chu 30(b)(6) deposition 44:01 topics."		
49:03 - 49:09 Clear	**Chu, Karen 2022-12-16** 49:03 Q. Right. But who was the 49:04 individual who ultimately came up with 49:05 the idea of dosing 2 milligrams 49:06 approximately every four weeks for the 49:07 first three months and then the 2 49:08 milligram dose approximately every eight 49:09 weeks once every two months thereafter?	00:00:17	KC7.22
49:13 - 50:02	**Chu, Karen 2022-12-16** 49:13 A. So again, Regeneron operates in 49:14 a, you know, cross-functional team 49:15 environment, so there was input given by 49:16 many different functions and many 49:17 different people. But George Yancopoulos 49:18 and Len Schleifer were definitely heavily 49:19 involved in these discussions and no 49:20 approval would have been needed to be 49:21 given by George to move ahead with the 49:22 study design. 49:23 Q. Right. I understand they had 49:24 to give approval, but who actually came 49:25 up with the idea of this particular 50:01 regimen in Regeneron's view? 50:02 A. I don't recall.	00:00:40	KC7.23
54:14 - 54:19	**Chu, Karen 2022-12-16** 54:14 Q. All right. So Ms. Chu, when it 54:15 comes to Regeneron's position with regard 54:16 to the '601 patent, does Regeneron have a 54:17 position as to who was responsible for 54:18 the conception of the full claims set 54:19 forth in Claim 1 of the '601 patent?	00:00:26	KC7.24
54:23 - 55:03	**Chu, Karen 2022-12-16** 54:23 A. George Yancopoulos is the named 54:24 inventor on the '601 patent.	00:00:16	KC7.25

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DESIGNATION	SOURCE	DURATION	ID
	54:25 Q. And why does Regeneron believe 55:01 that George Yancopoulos is the person who 55:02 conceived of the methods set forth in 55:03 Claim 1 of the '601 patent?		
55:07 - 55:21	**Chu, Karen 2022-12-16**	00:00:46	KC7.26
	55:07 A. George has always and continues 55:08 to play a very hands-on role in all 55:09 research and development, including the 55:10 development of aflibercept, and he was 55:11 personally involved in many, many 55:12 discussions related to the development of 55:13 aflibercept across all phases of clinical 55:14 trials, including the design of the Phase 55:15 III studies. 55:16 Q. So is it Regeneron's position 55:17 that the reason -- that the reason for 55:18 George Yancopoulos being the named 55:19 inventor is because he's the one who did 55:20 the signoff on the Phase III clinical 55:21 design study?		
55:25 - 56:06	**Chu, Karen 2022-12-16**	00:00:19	KC7.27
	55:25 Q. Sorry, Phase III clinical study 56:01 design. 56:02 A. So my knowledge is that George 56:03 had tremendous input and ultimately it 56:04 was his decision to move forward with the 56:05 final study design for the VIEW 1 and the 56:06 VIEW 2 studies.		
56:23 - 57:04	**Chu, Karen 2022-12-16**	00:00:17	KC7.28
	56:23 Q. Are there any documents that 56:24 showed that it was George Yancopoulos as 56:25 opposed to someone else who specifically 57:01 put together the 2 milligrams every four 57:02 weeks for the first six months followed 57:03 by 2 milligrams once every eight weeks or 57:04 every two months thereafter?		
57:10 - 57:11	**Chu, Karen 2022-12-16**	00:00:04	KC7.29
	57:10 A. Off the top of my head, I don't 57:11 recall specific documents.		

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DESIGNATION	SOURCE	DURATION	ID
64:18 - 64:20	**Chu, Karen 2022-12-16** 64:18 Q. Did you try to reach out to 64:19 Dr. Cedarbaum to prepare as a 30(b)(6) 64:20 witness?	00:00:06	KC7.30
64:24 - 65:07	**Chu, Karen 2022-12-16** 64:24 A. I did not reach out to 64:25 Dr. Cedarbaum in preparation for this 65:01 deposition. 65:02 Q. What about Mr. Ingerman, Avner 65:03 Ingerman? 65:04 A. Right, Avner Ingerman. 65:05 Q. Wasn't he also one of the 65:06 individuals who was in favor of the 65:07 eight-week interval?	00:00:18	KC7.31
65:11 - 65:17	**Chu, Karen 2022-12-16** 65:11 A. My recollection of 65:12 Dr. Ingerman's position at that time is 65:13 that he was lobbying for an as-needed or 65:14 PRN dosing regimen, although he was part 65:15 of many discussions about alternative 65:16 dosing regimens that could be employed. 65:17 Q. Such as?	00:00:22	KC7.32
65:21 - 65:22	**Chu, Karen 2022-12-16** 65:21 A. Such as every eight weeks or 65:22 other potential dosing regimens.	00:00:05	KC7.33
73:21 - 73:23	**Chu, Karen 2022-12-16** 73:21 Q. And what within the visual 73:22 acuity data prompted shortening the 73:23 interval from 12 weeks to eight?	00:00:09	KC7.34
74:01 - 74:17	**Chu, Karen 2022-12-16** 74:01 A. So within the visual acuity 74:02 data, even though visual acuity is a 74:03 highly variable measure and this was a 74:04 relatively small study, in that there 74:05 were about 30 patients per group, we 74:06 looked for trends to inform us of what's 74:07 happening. And my recollection is that 74:08 the most important aspect of the visual 74:09 acuity was that the groups that were	00:00:44	KC7.35

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DESIGNATION	SOURCE	DURATION	ID
	74:10 dosed with monthly injections first 74:11 overall had a greater gain in visual 74:12 acuity. 74:13 Secondly, that when those 74:14 patients were allowed to go longer than 74:15 four weeks without a dose, we saw some 74:16 decline in visual acuity over that 74:17 period.		
74:18 - 74:20	**Chu, Karen 2022-12-16**	00:00:09	KC7.36
	74:18 Q. Okay. And was the period a 74:19 12-week period, an eight-week period, or 74:20 was it a PRN period?		
74:24 - 75:02	**Chu, Karen 2022-12-16**	00:00:13	KC7.37
	74:24 A. So in this study, after week 74:25 12, patients were dosed PRN. So the 75:01 duration between that week 12 dose and 75:02 subsequent doses was variable.		
75:21 - 75:23	**Chu, Karen 2022-12-16**	00:00:06	KC7.38
	75:21 Q. Okay. Well, why go with eight 75:22 weeks as opposed to six weeks or just 75:23 sticking with monthly?		
76:02 - 76:23	**Chu, Karen 2022-12-16**	00:01:06	KC7.39
	76:02 A. So we did include two monthly 76:03 dosing groups in the VIEW 1 and VIEW 2 76:04 study. We tested two separate doses, .5 76:05 milligrams and 2 milligrams. As I 76:06 mentioned before, there were many 76:07 considerations that went into the study 76:08 design. And some of those considerations 76:09 have to do with the constraints of study 76:10 conduct. 76:11 So one aspect of the study is 76:12 we must conduct them as what we called 76:13 double-mask studies, and we perform sham 76:14 injections at visits where patients are 76:15 not receiving an active injection. And 76:16 it was impractical to include a group 76:17 where we had a six-week dosing interval 76:18 because it would have necessitated visits		

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DESIGNATION	SOURCE	DURATION	ID
	76:19 essentially every two weeks for all 76:20 patients. 76:21 Q. So the every eight weeks just 76:22 made the clinical trial design easier in 76:23 terms of maintaining the mask?		
77:01 - 77:04	**Chu, Karen 2022-12-16**	00:00:13	KC7.40
	77:01 A. It was both a dosing interval 77:02 that we felt was supported by the data 77:03 and also created a more practical way to 77:04 conduct the study.		
79:16 - 79:25	**Chu, Karen 2022-12-16**	00:00:28	KC7.41
	79:16 Q. Now, in the '601 patent, Claim 79:17 10, we have the same dosing regimen, but 79:18 this time it's for a method of treating 79:19 diabetic macular edema in a patient in 79:20 need thereof. 79:21 Who was the one who -- what is 79:22 Regeneron's position as to who was the 79:23 person who actually came up with the idea 79:24 of applying this regimen to the DME 79:25 indication?		
80:04 - 80:18	**Chu, Karen 2022-12-16**	00:00:55	KC7.42
	80:04 A. So this regimen is different in 80:05 that it is for 2 milligrams given every 80:06 four weeks for the first five injections, 80:07 followed by approximately once every 80:08 eight weeks or every two months. And my 80:09 recollection is that, again, there were 80:10 several discussions about the optimal 80:11 study design for treating diabetic 80:12 macular edema. And those conversations 80:13 would have included both people from the 80:14 clinical team, as well as senior 80:15 management. 80:16 Q. Right. Who decided that the 80:17 dosing was going to be for the first five 80:18 injections as opposed to three or four?		
80:22 - 80:24	**Chu, Karen 2022-12-16**	00:00:07	KC7.43
	80:22 A. My recollection is that George		

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DESIGNATION	SOURCE	DURATION	ID
	80:23 Yancopoulos made that decision. 80:24 Q. Is that documented anywhere?		
81:03 - 81:04	**Chu, Karen 2022-12-16** 81:03 A. I don't recall if there is 81:04 specific documentation of that.	00:00:03	KC7.44
88:08 - 88:12	**Chu, Karen 2022-12-16** 88:08 Q. If you can take a look at the 88:09 '601 patent, is the clinical trial 88:10 protocol for the Phase III VIVID or VISTA 88:11 studies set forth in any of the patent 88:12 examples?	00:00:15	KC7.45
88:15 - 88:19	**Chu, Karen 2022-12-16** 88:15 A. To answer that question, I 88:16 would have to go through the entire 88:17 patent, is that something I should do? 88:18 Q. Sure. You can start with 88:19 example 1 which begins at Column 8.	00:00:13	KC7.46
88:20 - 89:06	**Chu, Karen 2022-12-16** 88:20 (Witness reviews document.) 88:21 A. So in my review of patent '601, 88:22 I do not see a description or the VIVID 88:23 and VISTA trials given as an example. 88:24 But I do see the Phase II clinical trial 88:25 in diabetic macular edema described as 89:01 example 5. 89:02 Q. And if I understand you, it was 89:03 the data from this Phase II study that 89:04 justified the dosing regimen for the 89:05 VIVID and VISTA studies for diabetic 89:06 retinopathy?	00:00:37	KC7.47
89:09 - 89:15	**Chu, Karen 2022-12-16** 89:09 A. So data from this Phase II 89:10 study did inform decisions regarding the 89:11 VIVID and VISTA study designs. 89:12 Q. Okay. And why is it that 89:13 Regeneron believed that the DME data 89:14 could be transferred over to the diabetic 89:15 retinopathy indication?	00:00:32	KC7.48
89:18 - 90:06	**Chu, Karen 2022-12-16**	00:00:41	KC7.49

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	89:18 A. So as I mentioned, data from 89:19 the VIVID and VISTA studies included a 89:20 secondary endpoint of a proportion of 89:21 patients with two-or-more-step 89:22 improvement in diabetic retinopathy. 89:23 Patients with diabetic macular 89:24 edema do have underlying diabetic 89:25 retinopathy at various severities. And 90:01 we did see a statistically significant 90:02 outcome of improvement in patients that 90:03 were treated with aflibercept in the 90:04 VIVID and VISTA studies -- I'm sorry, 90:05 yes, in the VIVID and VISTA studies, 90:06 sorry.		KC7.49
98:05 - 98:12	**Chu, Karen 2022-12-16**	00:00:07	KC7.50
D204.1	98:05 (Defendant's Exhibit 204, 98:06 Document Bates stamped MYL-AFL 5010 98:07 through 18, was so marked for 98:08 identification, as of this date.) 98:09 Q. Let me know when you have that 98:10 exhibit in front of you. 98:11 A. I have Exhibit 204 in front of 98:12 me.		
111:06 - 111:16	**Chu, Karen 2022-12-16**	00:00:38	KC7.51
Clear	111:06 Q. I would like to take a look at 111:07 Claim 6 of the '601 patent. 111:08 A. Okay. I see that. 111:09 Q. Yeah, and so here again, I just 111:10 have the question, what can be done to 111:11 the dosing regimen in Claim 1 to ensure 111:12 that a patient is going to be able to 111:13 meet these requirements of Claim 5 and 111:14 Claim 6, and specifically using this 111:15 measurement technique that's set forth in 111:16 Claim 6?		
111:19 - 111:24	**Chu, Karen 2022-12-16**	00:00:23	KC7.52
	111:19 A. So I would respond the same 111:20 way, that the response to treatment is 111:21 highly variable with individual patients. 111:22 Q. How are we going to know then		

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	111:23 if an individual patient actually meets 111:24 the standard?		
112:03 - 112:10	**Chu, Karen 2022-12-16**	00:00:20	KC7.53
	112:03 A. So in the treatment and 112:04 monitoring of an individual patient with 112:05 neovascular age-related macular 112:06 degeneration, visual acuity would be 112:07 assessed prior to treatment initiation, 112:08 and at an interval deemed appropriate by 112:09 the treating physician during the course 112:10 of treatment.		
115:01 - 115:03	**Chu, Karen 2022-12-16**	00:00:09	KC7.54
D205.1	115:01 Q. Ms. Chu, can you take a look at 115:02 DX 205 and confirm it's the FDA-approved 115:03 EYLEA labeling?		
115:07 - 115:09	**Chu, Karen 2022-12-16**	00:00:14	KC7.55
	115:07 A. So I have Exhibit 205 in front 115:08 of me and this appears to be the EYLEA 115:09 USPI revised as of May 2019.		
130:11 - 130:18	**Chu, Karen 2022-12-16**	00:00:26	KC7.56
Clear	130:11 Q. Okay. Well, are you aware of 130:12 any change to the formulation description 130:13 that appears here as compared to when the 130:14 EYLEA product was first approved in 2011? 130:15 A. In my experience and knowledge, 130:16 I'm not aware of any changes to the 130:17 formulation as described here in the 130:18 USPI.		
137:20 - 138:02	**Chu, Karen 2022-12-16**	00:00:15	KC7.57
	137:20 Q. Okay. And then we got George 137:21 Yancopoulos, who is listed at least on 137:22 this occupancy chart the CSO; is he still 137:23 the CSO today or does he have a better 137:24 title? 137:25 A. My understanding today, he 138:01 still has the title chief scientific 138:02 officer.		
140:23 - 140:25	**Chu, Karen 2022-12-16**	00:00:05	KC7.58
	140:23 Q. Okay. Anything, though, that		

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DESIGNATION	SOURCE	DURATION	ID
	140:24 would justify having the longer dosing 140:25 interval that you recall?		
141:03 - 141:18	**Chu, Karen 2022-12-16**	00:00:56	KC7.59
	141:03 A. I can't remember if this was 141:04 specifically in Neil's purview, but we 141:05 did know that based on the aflibercept 141:06 molecule, comparing to Lucentis, that it 141:07 did have a longer half life in the eye of 141:08 animals. And so that gave us an 141:09 indication that potentially a longer 141:10 dosing interval might be possible, but 141:11 certainly animal studies are only 141:12 somewhat translatable to human studies. 141:13 Q. And then from Regeneron's 141:14 perspective, which clinical trial was it 141:15 that allowed you to conclude that 141:16 aflibercept might have a longer half life 141:17 in the human eye that might justify a 141:18 longer dosing interval?		
141:21 - 142:06	**Chu, Karen 2022-12-16**	00:00:41	KC7.60
	141:21 A. So we -- during the course of 141:22 EYLEA clinical development, we did not 141:23 measure half life in the human eye. That 141:24 would have required sampling from ocular 141:25 fluids, which to do serially in patients 142:01 is very difficult and causes additional 142:02 safety risk for patients. So the data 142:03 from the 0508 or CLEAR-IT 2 study was 142:04 really the clinical data that we looked 142:05 at in order to decide which dosing 142:06 regimens to test in Phase III.		
143:14 - 143:22	**Chu, Karen 2022-12-16**	00:00:32	KC7.61
D207.1	143:14 Q. Okay. Can you confirm that 143:15 Exhibit 207 is a Friday, January 30th, 143:16 2004 e-mail from Jesse Cedarbaum to you 143:17 and others involving what was described 143:18 as draft VEGF-Trap AMD press and some 143:19 thoughts on the release of an AMD trial? 143:20 A. I see that e-mail is dated 143:21 Friday, January 30th, 2004 and that I'm		

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DESIGNATION	SOURCE	DURATION	ID
	143:22 one of the recipients of e-mail.		
144:22 - 144:24	**Chu, Karen 2022-12-16**	00:00:07	KC7.62
	144:22 Q. Okay. Was it common for 144:23 Regeneron to prepare press releases when 144:24 they were about to start clinical trials?		
145:02 - 145:06	**Chu, Karen 2022-12-16**	00:00:14	KC7.63
	145:02 A. Regeneron was a small company 145:03 back then, so the initiation of a 145:04 clinical development program would have 145:05 been something that we would have 145:06 disclosed.		
150:02 - 150:10	**Chu, Karen 2022-12-16**	00:00:23	KC7.64
D209.1	150:02 Do you have Exhibit 209 in 150:03 front of you? 150:04 A. Yes, I have Exhibit 209 in 150:05 front of me. 150:06 Q. Can you confirm the top e-mail 150:07 was copied to you and others on Tuesday, 150:08 August 31st, 2004? 150:09 A. Yes, I'm on the cc line of this 150:10 e-mail dated August 31st, 2004.		
152:02 - 152:07	**Chu, Karen 2022-12-16**	00:00:15	KC7.65
Clear	152:02 Q. Macugen was dosing its product 152:03 intravitally, correct? 152:04 A. That is correct. 152:05 Q. Did these results cause 152:06 Regeneron to start thinking more closely 152:07 of doing an intravitreal injection?		
152:10 - 152:24	**Chu, Karen 2022-12-16**	00:00:47	KC7.66
	152:10 A. I believe that the results from 152:11 the Macugen trials gave us more 152:12 information about the safety and 152:13 feasibility of intravitreal injections 152:14 given regularly to these, to the -- to 152:15 AMD patients over the course of a year of 152:16 treatment. 152:17 Q. Did the Macugen results give 152:18 you any sense that there might be more 152:19 willingness in the marketplace to accept		

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DESIGNATION	SOURCE	DURATION	ID
	152:20 an intravitreal injection? 152:21 A. The Macugen results from these 152:22 Phase III studies definitely supported 152:23 that intravitreal administration of a 152:24 product in wet AMD patients was possible.		
153:17 - 153:23	**Chu, Karen 2022-12-16** 153:17 Q. All right. And at this time it 153:18 was known to Regeneron that ranibizumab 153:19 was also out there in Phase III trials, 153:20 right? 153:21 A. Yes, the Lucentis trials were 153:22 being conducted concurrently at this 153:23 time.	00:00:16	KC7.67
154:03 - 154:11	**Chu, Karen 2022-12-16** 154:03 Q. And it also mentions at the end 154:04 of the paragraph that Regeneron's 154:05 VEGF-Trap was also currently in clinical 154:06 and preclinical trials, right? 154:07 A. Yes, the last sentence is 154:08 "Other anti-angiogenic agents currently 154:09 in clinical and preclinical trials are 154:10 Angstrom's A6, OXiGene's CA4P and 154:11 Regeneron's VEGF-Trap."	00:00:23	KC7.68
154:12 - 154:15	**Chu, Karen 2022-12-16** 154:12 Q. Okay. At this point in time, 154:13 were you looking at the Lucentis dosing 154:14 regimen as one that you might want to 154:15 copy or emulate?	00:00:09	KC7.69
154:18 - 154:21	**Chu, Karen 2022-12-16** 154:18 A. I would say at this time we 154:19 were monitoring the Lucentis clinical 154:20 development program closely from a 154:21 competitive intelligence perspective.	00:00:11	KC7.70
157:05 - 157:10	**Chu, Karen 2022-12-16** 157:05 Q. And certainly by the time we 157:06 got to the 2010 time frame, at the time 157:07 that you had submitted your Phase III 157:08 clinical trials, ranibizumab had been 157:09 shown to produce some consistent vision	00:00:20	KC7.71

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DESIGNATION	SOURCE	DURATION	ID
	157:10 gain, right, when injected intravitally?		
157:13 - 157:19	**Chu, Karen 2022-12-16** 157:13 A. So the pivotal Lucentis trials 157:14 in neovascular AMD were the Anchor and 157:15 Marina trials. And they demonstrated 157:16 vision gain with ranibizumab dosed every 157:17 four weeks or monthly for the -- for a 157:18 year, so week 52 was their primary 157:19 endpoint.	00:00:19	KC7.72
159:12 - 160:01	**Chu, Karen 2022-12-16** 159:12 (Defendant's Exhibit 210, 159:13 Document Bates stamped RGN-EYLEA-MYLAN 159:14 540875 through 877, was so marked for 159:15 identification, as of this date.) 159:16 EXAMINATION (Continued) 159:17 BY MS. MAZZOCHI: 159:18 Q. Do you have that exhibit before 159:19 you? 159:20 A. Yes, I have Exhibit 210. 159:21 Q. Can you confirm that Exhibit 159:22 210 contains an e-mail string including 159:23 an e-mail from Ilham Zoughi, Z-O-U-G-H-I, 159:24 to you and others dated March 3rd, 2005? 159:25 A. Yes, I see that I'm a recipient 160:01 of this e-mail from Ilham Zoughi.	00:00:27	KC7.73
D210.1			
161:04 - 161:09	**Chu, Karen 2022-12-16** 161:04 Q. If you look at the bottom line, 161:05 the author there said -- the study 161:06 clinician was quoted as saying, "We have 161:07 been injecting anti-VEGF drugs into the 161:08 eye for the past three years with very 161:09 encouraging results."	00:00:18	KC7.74
161:12 - 161:23	**Chu, Karen 2022-12-16** 161:12 Q. Do you see that? 161:13 A. I do see that as part of the 161:14 quote here. 161:15 Q. Right, and that quote is 161:16 attributed to Philip J. Rosenfeld, M.D., 161:17 Ph.D.?	00:00:27	KC7.75

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DESIGNATION	SOURCE	DURATION	ID
	161:18 A. So this e-mail just said 161:19 Rosenfeld, which assume to mean Phil 161:20 Rosenfeld. 161:21 Q. Did Regeneron also reach out to 161:22 get input from Phil Rosenfeld in the 161:23 context of its clinical trial work?		
162:02 - 162:07 Clear	**Chu, Karen 2022-12-16** 162:02 A. Dr. Rosenfeld was a respected 162:03 key opinion leader in the retina 162:04 community, and he is someone that we 162:05 interacted with occasionally to discuss 162:06 aspects of the clinical development 162:07 program.	00:00:16	KC7.76
162:08 - 162:18	**Chu, Karen 2022-12-16** 162:08 Q. Do you recall there being any 162:09 impact within Regeneron when it was 162:10 reported that Avastin, a VEGF inhibitor, 162:11 was producing positive results in the 162:12 eye? 162:13 A. I don't remember this study or 162:14 the data from this study having a 162:15 specific impact at Regeneron. 162:16 Q. All right. But what about 162:17 Avastin generally, the experience that 162:18 clinicians were having with Avastin?	00:00:32	KC7.77
162:21 - 162:25	**Chu, Karen 2022-12-16** 162:21 Q. Injecting it into the eye to 162:22 get -- to stop vision loss? 162:23 A. So this press release is 162:24 referring to systemic administration of 162:25 Avastin.	00:00:13	KC7.78
163:01 - 163:14	**Chu, Karen 2022-12-16** 163:01 Q. Right. 163:02 A. But Dr. Rosenfeld was involved 163:03 in running his own investigator-initiated 163:04 studies with intravitreal Avastin. 163:05 Q. Right, right. And he indicates 163:06 in this document at least that he had 163:07 been doing that for at least three years?	00:00:43	KC7.79

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DESIGNATION	SOURCE	DURATION	ID
	163:08 A. That is what the document says. 163:09 Q. Right. So did the fact that 163:10 someone like Dr. Rosenfeld and others 163:11 were injecting Avastin directly into the 163:12 eye, did that influence their thinking as 163:13 to whether it would be useful to dose 163:14 VEGF-Trap into the eye?		
163:17 - 163:22	**Chu, Karen 2022-12-16**	00:00:17	KC7.80
	163:17 A. Dr. Rosenfeld, as well as other 163:18 retinal specialists in the community, 163:19 provided information that gave Regeneron 163:20 more confidence regarding the feasibility 163:21 of moving forward with an intravitreally 163:22 delivered product.		
169:13 - 170:15	**Chu, Karen 2022-12-16**	00:01:34	KC7.81
	169:13 Q. Okay. 169:14 A. So the study in example 1 was 169:15 referred to as the CLEAR-IT 1 study. The 169:16 study in example 2 was the CLEAR-IT 2 169:17 study. 169:18 Q. Okay. Perfect. Thank you. 169:19 And then if we go on to the 169:20 next column, example 4, the Phase III 169:21 clinical trials, was that the VIEW 1 169:22 study or VIEW 2? 169:23 A. So this section under example 4 169:24 refers to two parallel Phase III clinical 169:25 trials carried out to investigate the use 170:01 of VEGF-T to treat patients with the 170:02 neovascular form of age-related macular 170:03 degeneration, so this section appears to 170:04 be referring to both the VIEW 1 and the 170:05 VIEW 2 studies. 170:06 Q. Okay. And then if you can jump 170:07 forward to column 14, there is an example 170:08 5 provided there. Did that clinical 170:09 study also have a name? 170:10 A. Example 5 is the Phase II 170:11 clinical trial of VEGF-T in subjects with 170:12 diabetic macular edema. This study was		

DESIGNATION	SOURCE	DURATION	ID
	170:13 referred to as the DaVinci trial. 170:14 Q. Okay. And then example 6, did 170:15 that clinical trial have a name?		
170:16 - 170:23	**Chu, Karen 2022-12-16** 170:16 A. So in example 6, it's referring 170:17 to a randomized multi-centered double- 170:18 masked trial in treatment of patients 170:19 with macular edema secondary to CRVO. 170:20 And I believe this is referring 170:21 to a study that we called the Copernicus 170:22 study, although there was a second CRVO 170:23 study conducted called the Galileo study.	00:00:24	KC7.82
171:05 - 171:19	**Chu, Karen 2022-12-16** 171:05 (Defendant's Exhibit 212, 171:06 Document Bates stamped RGN-EYLEA-MYLAN 171:07 634608 through 611, was so marked for 171:08 identification, as of this date.) 171:09 Q. Can you confirm this is a D212.1 171:10 document with an e-mail string with the 171:11 first one dated Sunday, January 8th, 171:12 2006, regarding an AMD expert meeting 171:13 from Neil Stahl to Jesse Cedarbaum, you 171:14 and others? 171:15 A. I can confirm that the date of 171:16 this e-mail is Sunday, January 8th, 2006. 171:17 The subject is regarding AMD expert 171:18 meeting. It's from Neil Stahl. And I'm 171:19 one of the recipients of this e-mail.	00:00:34	KC7.83
173:06 - 173:13	**Chu, Karen 2022-12-16** 173:06 Q. Okay. One of the other 173:07 questions to ask these experts was "Do 173:08 they think that the PIER regimen of 173:09 Lucentis will work." 173:10 Do you see that? 173:11 A. I do see that question. 173:12 Q. What was your understanding of 173:13 the PIER regimen for Lucentis?	00:00:16	KC7.84
173:17 - 173:23	**Chu, Karen 2022-12-16** 173:17 A. So the PIER study was an	00:00:24	KC7.85

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DESIGNATION	SOURCE	DURATION	ID
	173:18 investigator-initiated study conducted by 173:19 Dr. Phil Rosenfeld that, my understanding 173:20 of that regimen is that it was three 173:21 initial monthly doses of .3 milligrams of 173:22 Lucentis followed by quarterly dosing, so 173:23 every-three-month dosing.		
180:05 - 180:09	**Chu, Karen 2022-12-16**	00:00:03	KC7.86
	180:05 (Defendant's Exhibit 213, 180:06 Document Bates stamped RGN-EYLEA-MYLAN 180:07 634629 through 632, was so marked for 180:08 identification, as of this date.)		
D213.1	180:09 Q. Let me know when you have that.		
180:10 - 180:14	**Chu, Karen 2022-12-16**	00:00:06	KC7.87
	180:10 A. I have Exhibit 213 in front of 180:11 me. 180:12 Q. Are you identified as one of 180:13 the individuals who participated in this 180:14 advisory panel meeting?		
180:17 - 180:17	**Chu, Karen 2022-12-16**	00:00:03	KC7.88
	180:17 A. Give me a moment to review		
180:18 - 180:19	**Chu, Karen 2022-12-16**	00:00:06	KC7.89
	180:18 this. I am listed as one of the 180:19 Regeneron attendees for this meeting.		
181:06 - 181:15	**Chu, Karen 2022-12-16**	00:00:27	KC7.90
	181:06 Q. One of the items listed here 181:07 that Regeneron wanted to get the 181:08 consultant's impressions of was how will 181:09 Lucentis be used in practice, monthly as 181:10 in ANCHOR or MARINA, induction followed 181:11 by quarterly maintenance as in PIER or 181:12 induction followed by PIER and criteria 181:13 based dosing as in SAILOR. 181:14 Do you see that? 181:15 A. I do see that under 3A.		
183:14 - 183:24	**Chu, Karen 2022-12-16**	00:00:35	KC7.91
	183:14 Q. Now, the title of this was 183:15 "CLEAR-IT 3 Advisory Panel Meeting." 183:16 What was CLEAR-IT 3? 183:17 A. My recollection is that		

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DESIGNATION	SOURCE	DURATION	ID
	183:18 CLEAR-IT 3 was the initial name that 183:19 Dr. Cedarbaum wanted to give the Phase 183:20 III AMD studies. 183:21 Q. So CLEAR-IT 3 eventually became 183:22 known as the VIEW 1 and VIEW 2 studies? 183:23 A. The Phase III studies were 183:24 eventually named VIEW 1 and VIEW 2, yes.		
184:22 - 184:25	**Chu, Karen 2022-12-16**	00:00:03	KC7.92
D214.1	184:22 (Defendant's Exhibit 214, 184:23 Document Bates stamped RGN-EYLEA-MYLAN 184:24 569973 through 975, was so marked for 184:25 identification, as of this date.)		
185:04 - 185:12	**Chu, Karen 2022-12-16**	00:00:27	KC7.176
	185:04 Q. Can you confirm it's dated 185:05 Friday, February 10th, 2006 from Srilatha 185:06 Vuthoori to you and many others at 185:07 Regeneron? 185:08 A. This e-mail is dated Friday, 185:09 February 10th, 2006. The subject is 185:10 "Actions and Decisions VGT Team Meeting." 185:11 It's from Srilatha Vuthoori, and I am one 185:12 of the recipients.		
191:13 - 191:16	**Chu, Karen 2022-12-16**	00:00:15	KC7.93
D215.1	191:13 Q. Okay. Let me give you a 191:14 document that has production numbers 191:15 MYL-AFL 8703 through 8711, which I will 191:16 mark as DX 215.		
191:17 - 192:15	**Chu, Karen 2022-12-16**	00:00:54	KC7.94
	191:17 (Defendant's Exhibit 215, 191:18 Document Bates stamped MYL-AFL 8703 191:19 through 8711, was so marked for 191:20 identification, as of this date.) 191:21 A. I have Exhibit 215 in front of 191:22 me. 191:23 Q. Do you see the citation in the 191:24 upper right-hand corner says "WHO Drug 191:25 Information Volume 20, Number 2, 2006"? 192:01 A. I see that the document is 192:02 labeled in the upper right-hand corner		

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DESIGNATION	SOURCE	DURATION	ID
	192:03 "WHO Drug Information Volume 20, number 192:04 2, 2006." 192:05 Q. And then this was titled, 192:06 "International Non-Proprietary Names For 192:07 Pharmaceutical Substances." 192:08 A. I see the document is titled, 192:09 "International Non-Proprietary Names For 192:10 Pharmaceutical Substances." 192:11 Q. All right. Can you go ahead,		
D215.4	192:12 and turn to page 8706 as the Bates 192:13 number. It's page 118 within this 192:14 volume. And do you see a reference on 192:15 this page to aflibercept?		
192:16 - 192:18	**Chu, Karen 2022-12-16**	00:00:11	KC7.95
	192:16 A. Yes, I see on the second half 192:17 of the page there is a reference to 192:18 aflibercept.		
193:09 - 193:12	**Chu, Karen 2022-12-16**	00:00:18	KC7.96
Clear	193:09 In the context of your clinical 193:10 work did you ever use the term 193:11 "aflibercept" to refer to any chemical 193:12 structure other than VEGF Trap-Eye?		
193:15 - 194:01	**Chu, Karen 2022-12-16**	00:00:44	KC7.97
	193:15 A. So the terms VEGF-Trap, VGFT, 193:16 VEGF Trap-Eye, and aflibercept, depending 193:17 on the time period, were used somewhat 193:18 synonymously. VEGF Trap-Eye was almost 193:19 always used to distinguish between the 193:20 systemic formulation of aflibercept 193:21 versus the intravitreal formulation. 193:22 Q. Right. But the underlying 193:23 structure of aflibercept the molecule 193:24 didn't change whether it was VEGF 193:25 Trap-Eye or just VEGF-Trap or 194:01 aflibercept; is that fair?		
194:04 - 194:08	**Chu, Karen 2022-12-16**	00:00:15	KC7.98
	194:04 A. It is my understanding that the 194:05 active ingredient was the same in VEGF 194:06 Trap-Eye and aflibercept whether that was		

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DESIGNATION	SOURCE	DURATION	ID
	194:07 referring to the oncology product or the 194:08 intravitreally-delivered product.		
206:04 - 206:08	**Chu, Karen 2022-12-16**	00:00:14	KC7.99
D218.1	206:04 MS. MAZZOCHI: Okay. I would 206:05 like to mark as Defendant's Exhibit 206:06 218, a document with production 206:07 numbers RGN-EYLEA-MYLAN 553211 through 206:08 212.		
206:09 - 207:06	**Chu, Karen 2022-12-16**	00:00:54	KC7.100
	206:09 (Defendant's Exhibit 218, 206:10 Document Bates stamped RGN-EYLEA-MYLAN 206:11 553211 through 212, was so marked for 206:12 identification, as of this date.) 206:13 Q. And can you confirm this is a 206:14 May 9th, 2006 e-mail from Jesse Cedarbaum 206:15 to you and others discussing Rosenfeld's 206:16 Lucentis pronto press release? 206:17 A. This is an e-mail dated 206:18 Tuesday, May 9th, 2006 with "Subject: 206:19 Rosenfeld Lucentis Pronto Press Release," 206:20 from Jesse Cedarbaum and I am listed as 206:21 one of the recipients. 206:22 Q. Now, according to this press 206:23 release it says, "Open label on 206:24 Controlled Study of Lucentis showed 206:25 Improvement in Vision With Five to Six 207:01 Doses At One Year." 207:02 Do you see that? 207:03 A. I see that -- the title is 207:04 "Open Label on Controlled Study of 207:05 Lucentis Showed Improvement in Vision in 207:06 Five to Six Doses in One Year."		
208:03 - 208:18	**Chu, Karen 2022-12-16**	00:00:42	KC7.101
	208:03 Q. Now, one of the metrics that he 208:04 was using to evaluate vision improvement 208:05 is, according to the second paragraph, 208:06 "Average vision improved in the treated 208:07 eye almost two lines after one year. 208:08 Additional 82 percent of patients had the 208:09 same or better vision after one year and		

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DESIGNATION	SOURCE	DURATION	ID
	208:10 35 percent of patients experienced a 208:11 two-fold improvement of vision as defined 208:12 by gaining three lines of vision on a 208:13 standardized visual acuity chart." 208:14 Do you see that? 208:15 A. I do see where the press 208:16 release refers to an overall average 208:17 vision improved in the treated eye almost 208:18 two lines after one year.		
211:23 - 212:17 Clear	**Chu, Karen 2022-12-16** 211:23 Q. Do you recall whether anybody 211:24 ever talked about a dosing regimen that 211:25 you thought might be superior to the 212:01 FDA-approved regimen for Lucentis? 212:02 A. We thought it was possible that 212:03 aflibercept could be superior to 212:04 ranibizumab. And the design of the Phase 212:05 III clinical trials was such that we did 212:06 include a 2 milligram every four-week 212:07 dosing group as well as a .5 milligram 212:08 every four-week dosing group with the 212:09 ability, if we met noninferiority in 212:10 those groups, to then be able to test for 212:11 superiority. 212:12 And I should just clarify, that 212:13 that would have been true for all of the 212:14 groups, including the third treatment 212:15 group, which was three initial monthly 212:16 doses followed by a dosing every eight 212:17 weeks.	00:00:59	KC7.102
213:21 - 213:25	**Chu, Karen 2022-12-16** 213:21 Q. During your time at Regeneron, 213:22 has Regeneron identified any head-to-head 213:23 dosing regimen where it believes 213:24 aflibercept can demonstrate superiority 213:25 to Lucentis --	00:00:19	KC7.103
214:03 - 214:20	**Chu, Karen 2022-12-16** 214:03 Q. -- in a manner that the FDA or 214:04 clinicians would accept? 214:05 A. In the protocol T study, which	00:00:55	KC7.104

DESIGNATION	SOURCE	DURATION	ID
	214:06 was a study conducted by the Diabetic 214:07 Retinopathy Clinical Research Network 214:08 with aflibercept and ranibizumab and 214:09 Bevacizumab dosed in the same paradigm, 214:10 which was a different paradigm than 214:11 Regeneron has tested in our trials, 214:12 aflibercept was superior to both 214:13 ranibizumab and Bevacizumab. 214:14 Q. And in that particular dosing 214:15 regimen of aflibercept that you just 214:16 mentioned it was shown to be superior to 214:17 Lucentis, is that an FDA-approved dosing 214:18 regimen or no? 214:19 A. That dosing regimen is not 214:20 specifically reflected in our labeling.		
215:01 - 215:12	**Chu, Karen 2022-12-16**	00:00:26	KC7.105
	215:01 Q. Okay. Do you remember 215:02 generally what was, what they were doing 215:03 in that one, in terms of did it deviate 215:04 from monthly dosing, was it number of 215:05 injections? 215:06 A. My recollection is it that it 215:07 was monthly dosing for a certain number 215:08 of doses. And then criteria based dosing 215:09 based on the protocol -- 215:10 Q. Okay. 215:11 A. -- which allowed for a longer 215:12 treatment interval.		
216:02 - 216:15	**Chu, Karen 2022-12-16**	00:00:40	KC7.106
D219.1	216:02 (Defendant's Exhibit 219, 216:03 Document Bates stamped RGN-EYLEA-MYLAN 216:04 571549, was so marked for 216:05 identification, as of this date.) 216:06 Q. And can you confirm this is an 216:07 e-mail from Michael Roosevelt to you, 216:08 amongst others, dated Tuesday, May 9th, 216:09 2006? 216:10 A. Okay. I have Exhibit 219 and 216:11 the date of the e-mail is Tuesday, May 216:12 9th, 2006 with "Subject: Action Items,"		

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DESIGNATION	SOURCE	DURATION	ID
	216:13 May 9th, 2006, from Michael Roosevelt. 216:14 And I am one of the recipients of this 216:15 e-mail.		
217:05 - 217:09	**Chu, Karen 2022-12-16** 217:05 Q. Right. And then we have the 217:06 0508 study and that was one of the DME 217:07 studies? 217:08 A. 0508 was the Phase II study in 217:09 wet AMD with intravitreal aflibercept.	00:00:12	KC7.107
218:17 - 218:20 Clear	**Chu, Karen 2022-12-16** 218:17 Q. Okay. And what was the name of 218:18 that trial? 218:19 A. We referred to that as the 218:20 CLEAR-IT 2 trial.	00:00:06	KC7.108
219:04 - 219:24	**Chu, Karen 2022-12-16** 219:04 Q. Okay. Do you recall any 219:05 concerns expressed internally at 219:06 Regeneron about Aflibercept's ability to 219:07 achieve any efficacy endpoints by the 219:08 12-week -- with a 12-week dosing 219:09 interval? 219:10 A. Are you referring to during the 219:11 ongoing study? 219:12 Q. Yeah, either while the study 219:13 was conducted or afterwards. 219:14 A. So once we had the -- so this 219:15 e-mail is referring to a time when the 219:16 studies were ongoing. Once we received 219:17 data from the studies and analyzed it, we 219:18 did have some concerns that based on the 219:19 OCT data and an assessment of the visual 219:20 acuity data, that the 12-week interval 219:21 was one where we were seeing some loss of 219:22 efficacy over that duration. 219:23 Q. And how were you defining loss 219:24 of efficacy?	00:01:12	KC7.109
220:02 - 220:12	**Chu, Karen 2022-12-16** 220:02 A. So primarily, we were looking 220:03 at central retinal lesion thickness	00:00:38	KC7.110

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DESIGNATION	SOURCE	DURATION	ID
	220:04 measured by optical coherence tomography 220:05 which was a very quantitative measure of 220:06 the fluid in the retina. And one aspect 220:07 of that data is that we would see a rapid 220:08 reduction in retinal fluid after dosing 220:09 with aflibercept. And over the longer 220:10 time period without treatment, we would 220:11 see some of that fluid begin to 220:12 reaccumulate.		
222:03 - 222:17	**Chu, Karen 2022-12-16**	00:00:42	KC7.111
D220.1	222:03 Q. On this one, I would like to 222:04 start with the e-mail at the end of the 222:05 chain from George Yancopoulos to you and 222:06 others, dated Tuesday, May 16th, 2006. 222:07 So let me know when you're there. 222:08 A. I have Exhibit 220 in front of 222:09 me and I see the e-mail in the string 222:10 from George Yancopoulos dated Wednesday, 222:11 May 17th, 2006 and I am one of the 222:12 recipients. 222:13 Q. And they are also talking about 222:14 the pronto data, which was 222:15 Dr. Rosenfeld's Lucentis study, right? 222:16 A. Yes, this e-mail is referring 222:17 to the pronto study.		
222:23 - 223:12	**Chu, Karen 2022-12-16**	00:00:46	KC7.112
	222:23 Q. And it looks like 222:24 Dr. Yancopoulos is saying about the 222:25 pronto data, that "Lucentis was not 223:01 lasting for two months which could 223:02 provide a major opportunity for VEGF-Trap 223:03 interval advantage." 223:04 Do you see that? 223:05 A. Yes, so this is an e-mail in 223:06 the string dated Tuesday, May 16th, 2006, 223:07 "Subject: Pronto Data." 223:08 Q. Okay. Was Dr. Yancopoulos's 223:09 assessment of the Lucentis pronto data 223:10 something that caused everybody to start 223:11 saying, okay, we know Lucentis can't go		

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DESIGNATION	SOURCE	DURATION	ID
	223:12 for more than two months?		
223:15 - 224:01	**Chu, Karen 2022-12-16**	00:00:36	KC7.113
	223:15 A. So we were -- I don't recall 223:16 specifically if this data in any way 223:17 translated to further discussions about 223:18 the dosing regimens planned in the VIEW 1 223:19 and VIEW 2 studies. 223:20 Q. Well, he says "This indeed may 223:21 provide us a major opportunity for 223:22 VEGF-Trap interval advantage." 223:23 Did you look at that and get 223:24 excited and say, yeah, it will? Or was 223:25 it more like whatever, and you just 224:01 continued on your merry way?		
224:04 - 224:23	**Chu, Karen 2022-12-16**	00:01:04	KC7.114
	224:04 A. We were excited about the 224:05 possibility of aflibercept having a 224:06 longer treatment interval, based on the 224:07 properties of the molecule itself, as 224:08 well as the emerging data from the 224:09 clinical development program. 224:10 I believe that Lucentis was 224:11 approved in 2006 and was, because of 224:12 their clinical trial results, slated to 224:13 become standard of care. So I think 224:14 that, you know, it wasn't specifically 224:15 any outcome from Lucentis trials that 224:16 made us excited, but we were certainly 224:17 monitoring the competitive landscape 224:18 closely. 224:19 Q. What was your -- to your 224:20 recollection, what was Regeneron's 224:21 rationale for why the VEGF-Trap 224:22 aflibercept molecule would be able to 224:23 last longer as compared to Lucentis?		
224:25 - 225:21	**Chu, Karen 2022-12-16**	00:01:13	KC7.115
	224:25 Q. Ranibizumab. 225:01 A. My understanding of Regeneron's 225:02 rationale is that first aflibercept is a 225:03 larger molecule, and as a result has a		

DESIGNATION	SOURCE	DURATION	ID
	225:04 longer half life than Lucentis does as 225:05 well as the fact that we have a much, 225:06 much higher binding affinity and other 225:07 kinetic properties of binding to VEGF 225:08 that we felt would be advantageous for 225:09 aflibercept, and contribute to 225:10 potentially a longer duration of action. 225:11 Q. To date, as far as you're 225:12 aware, has Regeneron ever validated that 225:13 those two things, having a longer half 225:14 life and increased binding affinity 225:15 actually, is what's allowing aflibercept 225:16 to be dosed at these longer intervals as 225:17 compared to ranibizumab? 225:18 A. So the evidence we have of the 225:19 longer duration of action is from the 225:20 clinical trial results, based on outcomes 225:21 in the clinical studies.		
226:15 - 227:02	**Chu, Karen 2022-12-16**	00:00:45	KC7.116
	226:15 Q. If we can go to the front page 226:16 of Defendant's Exhibit 220, you were also 226:17 cc'd again on the e-mail string, this 226:18 time on May 17th, 2006 from George 226:19 Yancopoulos about the pronto data. And 226:20 he was responding to an e-mail from Avner 226:21 Ingerman. 226:22 Do you see that? 226:23 A. I do see the e-mail dated 17th 226:24 May 2006, from George to Avner and 226:25 others, where Avner is responding to an 227:01 e-mail from -- or sorry, George is 227:02 responding to an e-mail from Avner.		
227:20 - 227:24	**Chu, Karen 2022-12-16**	00:00:15	KC7.117
	227:20 Q. Now, Avner was discussing, not 227:21 just pronto, but also the MARINA and 227:22 ANCHOR trials. Those were official 227:23 Lucentis trials run by Genentech, 227:24 right?		
228:01 - 228:13	**Chu, Karen 2022-12-16**	00:00:33	KC7.118
	228:01 A. The MARINA and ANCHOR studies		

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DESIGNATION	SOURCE	DURATION	ID
	228:02 were the studies sponsored by Genentech 228:03 for Lucentis in neovascular AMD. 228:04 Q. "In discussing those trials, it 228:05 may suggest that the so-called clinician 228:06 PRN practice following 'induction dose' 228:07 is as good as monthly injections for at 228:08 least the first year, and that is 228:09 probably the take home message that the 228:10 market will follow." 228:11 Do you see that? 228:12 A. I do see that sentence in the 228:13 e-mail.		
228:14 - 229:07	**Chu, Karen 2022-12-16**	00:00:51	KC7.119
	228:14 Q. Do you know whether anybody 228:15 agreed or disagreed with Avner's 228:16 assessments that that's how clinicians 228:17 would likely respond to this data? 228:18 A. Sorry, could you just restate 228:19 the question? 228:20 Q. Sure. Do you recall within 228:21 Regeneron whether people agreed or 228:22 disagreed with Dr. Ingerman's view that 228:23 clinicians would probably perceive the 228:24 clinician PRN practice following the 228:25 induction dose was as good as monthly 229:01 injections for at least the first year, 229:02 when it came to ranibizumab? 229:03 A. My understanding is that Dr. 229:04 Yancopoulos strongly disagreed with the 229:05 concept that PRN dosing was as good as 229:06 monthly dosing as studied in the ANCHOR 229:07 and MARINA trials.		
Clear			
232:06 - 232:09	**Chu, Karen 2022-12-16**	00:00:13	KC7.120
	232:06 Q. So why did Dr. Yancopoulos 232:07 agree to any type of PRN-type dosing in 232:08 the later part of the VIEW studies, if he 232:09 was adamant that it wasn't going to work?		
232:12 - 232:18	**Chu, Karen 2022-12-16**	00:00:22	KC7.121
	232:12 A. My recollection is that the 232:13 most critical portion of the study and		

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DESIGNATION	SOURCE			DURATION	ID
	232:14		the portion of the studies that defined		
	232:15		our initial-dosing regimen in our		
	232:16		application to the FDA was the one-year		
	232:17		data from the VIEW 1 and the VIEW 2		
	232:18		studies.		
245:02 - 245:20	**Chu, Karen 2022-12-16**			00:00:47	KC7.122
	245:02		(Defendant's Exhibit 222,		
	245:03		Document Bates stamped		
	245:04		RGN-EYLEA-MYLAN-00523302 through 304,		
	245:05		was so marked for identification, as		
	245:06		of this date.)		
D222.1	245:07	Q.	Let me know when you have that.		
	245:08	A.	I have Exhibit 222 in front of		
	245:09		me.		
	245:10	Q.	And can you confirm that you		
	245:11		were forwarded by Jesse Cedarbaum on or		
	245:12		around September 5, 2006, a message -- an		
	245:13		e-mail message involving Jesse Cedarbaum		
	245:14		and Phil Rosenfeld, dated September is,		
	245:15		2006?		
	245:16	A.	So I see the second sort of		
	245:17		message in this string as a forwarded		
	245:18		message from Jesse Cedarbaum dated the		
	245:19		5th of September 2006. It was primarily		
	245:20		to Len Schleifer, but I am copied.		
247:10 - 248:07	**Chu, Karen 2022-12-16**			00:01:03	KC7.123
	247:10	Q.	Okay. Well, one of the things		
	247:11		that Dr. Rosenfeld told Jesse Cedarbaum		
	247:12		which was passed on to you, is he said		
	247:13		"You have a chance of using a 4-milligram		
	247:14		dose which is a 4-fold molar excess over		
	247:15		Lucentis with a good chance of better		
	247:16		durability. The more I thought about		
	247:17		your dilemma, I would go with the 2		
	247:18		milligram and 4 milligram dose every two		
	247:19		weeks or four weeks for a fixed number of		
	247:20		doses. Then see the patients back every		
	247:21		four weeks and dose as needed. With the		
	247:22		competition closing in on you, I think		
	247:23		your only choice is to go for the gold		

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	247:24 and design a Phase III now."		
	247:25 Do you see that?		
	248:01 A. I do see where the e-mail		
	248:02 states that phrasing.		
	248:03 Q. Do you remember internally ever		
	248:04 discussing the possibility of using a 2		
	248:05 milligram dose in your Phase III clinical		
	248:06 trials before Jesse Cedarbaum got this		
	248:07 feedback from Dr. Rosenfeld?		
248:11 - 249:02	**Chu, Karen 2022-12-16**	00:00:41	KC7.124
	248:11 A. I don't recall specifically the		
	248:12 timing of the discussions regarding dose		
	248:13 selection for Phase III.		
	248:14 Q. If you look at the top e-mail,		
	248:15 this is Len Schleifer saying this is Phil		
	248:16 Rosenfeld's view of our diabetes		
	248:17 opportunity. And then he says in the		
	248:18 second line Jesse showed him the		
	248:19 four-week, five-patient DME data, which		
	248:20 showed a nice response at four weeks and		
	248:21 then a small loss by six weeks.		
	248:22 Do you see that?		
	248:23 A. I do see where that sentence		
	248:24 is.		
	248:25 Q. Do you know which clinical		
	249:01 trial data that was, that was the four		
	249:02 week, five-patient DME?		
249:07 - 249:10	**Chu, Karen 2022-12-16**	00:00:09	KC7.125
	249:07 A. My assessment is that is		
Clear	249:08 referring to the 0512 study, which was		
	249:09 the Phase I study with intravitreal		
	249:10 aflibercept in DME.		
250:14 - 251:02	**Chu, Karen 2022-12-16**	00:00:43	KC7.126
	250:14 Q. Is it possible -- well, do you		
	250:15 recall who was responsible for designing		
	250:16 the Phase II DME study that's referred to		
	250:17 here in example 5 of the '601 patent?		
	250:18 A. So again, I don't recall		
	250:19 specifically who was involved at that		
	250:20 time, but it would have included members		

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DESIGNATION	SOURCE	DURATION	ID
	250:21 of the clinical development group, 250:22 including myself and Dr. Vitti. Alyson 250:23 Berlinger, I believe, was the study 250:24 director. We consulted with our 250:25 regulatory colleagues, as well as senior 251:01 management and others regarding the study 251:02 design.		
257:13 - 257:15	**Chu, Karen 2022-12-16**	00:00:16	KC7.127
D224.1	257:13 I would like to mark as DX 224, 257:14 a document with production numbers 257:15 RGN-EYLEA-MYLAN 635438 through 449.		
258:03 - 258:04	**Chu, Karen 2022-12-16**	00:00:03	KC7.128
	258:03 Q. What was the purpose of the 258:04 global project team?		
258:07 - 258:15	**Chu, Karen 2022-12-16**	00:00:27	KC7.129
	258:07 A. The global project team was a 258:08 cross-functional team established as part 258:09 of the Bayer collaboration to oversee 258:10 development for aflibercept with our 258:11 co-development partner. 258:12 Q. And did the Bayer people have 258:13 input into what your Phase III clinical 258:14 trial would look like in terms of dosing 258:15 regimen?		
258:18 - 258:23	**Chu, Karen 2022-12-16**	00:00:16	KC7.130
	258:18 A. As part of the Bayer 258:19 collaboration, they had input into 258:20 aspects of the clinical development 258:21 planning, including study designs. But 258:22 the ultimate scientific decision-making 258:23 remained with Regeneron.		
268:12 - 269:05	**Chu, Karen 2022-12-16**	00:00:51	KC7.131
	268:12 (Defendant's Exhibit 226, 268:13 Document Bates stamped RGN-EYLEA-MYLAN 268:14 631170 through 631175, was so marked 268:15 for identification, as of this date.) 268:16 Q. Can you confirm on the first D226.1 268:17 page of DX 226, there is an e-mail from 268:18 you dated March 29th, 2007 to Jesse		

DESIGNATION	SOURCE	DURATION	ID
	268:19 Cedarbaum, where you were forwarding the 268:20 conversation on VEGF-Trap executive 268:21 summary of scientific advice meeting with 268:22 Swedish MPA? 268:23 A. Yes, so I have Exhibit 226 in 268:24 front of me. And I see the second e-mail 268:25 in the string is a forwarded e-mail from 269:01 me to Jesse Cedarbaum on the 29th of 269:02 March 2007 with the "Subject: VEGF-Trap 269:03 Executive Summary of Scientific Advice 269:04 Meeting with Swedish MPA," on the 28th 269:05 March '07.		
269:20 - 270:05	**Chu, Karen 2022-12-16** 269:20 Q. Well, if we take a look at 269:21 Jesse Cedarbaum's responsive e-mail, can 269:22 you confirm that that's dated March 29th, 269:23 2007, and went to individuals such as 269:24 Avner Ingerman and George Yancopoulos? 269:25 A. Yes. The first e-mail in the 270:01 string here is dated Thursday, March 270:02 29th, 2007 forwarding VEGF-Trap executive 270:03 summary of scientific advice meeting with 270:04 Swedish MPA from Jesse Cedarbaum to Peter 270:05 Powchik, Avner Ingerman and others.	00:00:39	KC7.132
275:04 - 275:10 Clear	**Chu, Karen 2022-12-16** 275:04 Q. Sure. Is Regeneron aware of 275:05 anyone who put together for the Phase III 275:06 VIEW 1, VIEW 2 clinical trial design, a 275:07 2-milligram dose and an eight-week dosing 275:08 interval before Dr. Cedarbaum's e-mail 275:09 we're looking at here of March 29th, 275:10 2007?	00:00:20	KC7.133
275:14 - 275:23	**Chu, Karen 2022-12-16** 275:14 A. I don't recall exactly the 275:15 discussions around the eight-week 275:16 interval or whether Dr. Cedarbaum by 275:17 virtue of this e-mail was the first 275:18 person to suggest the eight-week 275:19 interval. 275:20 Q. Can Regeneron identify anybody	00:00:31	KC7.134

DESIGNATION	SOURCE	DURATION	ID
	275:21 who did it, who put those two pieces 275:22 together, a 2- milligram dose/eight-week 275:23 interval before Dr. Cedarbaum did?		
276:05 - 276:09	**Chu, Karen 2022-12-16** 276:05 A. I can't speak on behalf of 276:06 Regeneron, I can only speak for myself, 276:07 and I do not recall a person who 276:08 specifically put that together in this 276:09 time frame.	00:00:10	KC7.135
276:18 - 277:12	**Chu, Karen 2022-12-16** 276:18 (Defendant's Exhibit 227, 276:19 Document Bates stamped RGN-EYLEA-MYLAN 276:20 631182, was so marked for 276:21 identification, as of this date.) 276:22 Q. And Ms. Chu, if you can confirm 276:23 this is an e-mail from Kathleen Lawrence 276:24 to you and others, dated Monday, April 276:25 2nd, 2007? 277:01 A. So I have Exhibit 227 in front 277:02 of me with a date April 2nd, 2007. 277:03 "Subject: Decisions and Actions, AMD 277:04 Phase III Program Meeting - April 2nd, 277:05 '07" from Kathleen Lawrence, and I am a 277:06 recipient of this e-mail. 277:07 Q. Do you recall if you were a 277:08 participant in this AMD Phase III program 277:09 meeting on April 2nd, 2007? 277:10 A. I don't recall this specific 277:11 meeting. But in my role, I would have 277:12 attended such meetings.	00:00:53	KC7.136
D227.1			
279:16 - 279:21	**Chu, Karen 2022-12-16** 279:16 Q. Okay. Now, the third bullet 279:17 point down says -- this is for the first 279:18 time we see this: "2 milligrams Q8 weeks 279:19 with PIER lead-in (dose monthly for first 279:20 three months)." 279:21 Do you see that?	00:00:13	KC7.137
279:24 - 280:06	**Chu, Karen 2022-12-16** 279:24 A. I do see the third bullet	00:00:20	KC7.138

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DESIGNATION	SOURCE	DURATION	ID
	279:25 states: "2 milligram Q8 weeks with PIER 280:01 lead-in (dose monthly for first three 280:02 months)." 280:03 Q. All right. Who put, who 280:04 actually assembled that particular 280:05 regimen as one of the arms to consider 280:06 for the VIEW 1, Phase III clinical trial?		
280:16 - 280:17	**Chu, Karen 2022-12-16** 280:16 A. I don't recall specifically who 280:17 proposed that dosing regimen.	00:00:06	KC7.139
285:09 - 286:04	**Chu, Karen 2022-12-16** 285:09 (Defendant's Exhibit 228, 285:10 Document Bates stamped RGN-EYLEA-MYLAN 285:11 526319 through 321, was so marked for 285:12 identification, as of this date.) 285:13 Q. This is an e-mail dated 285:14 Wednesday, April 4th, 2007, from George 285:15 Yancopoulos to Darlene Jody; do you have 285:16 that? 285:17 A. Yes, so I have Exhibit 228, 285:18 dated Wednesday, April 4th, 2007 with the 285:19 "Subject: Summary of Issues For Call, 285:20 AMD P3 Planning," from George Yancopoulos 285:21 to Darlene Jody. 285:22 Q. Now, earlier in the deposition 285:23 today, you referred to an e-mail that you 285:24 recalled seeing that you discussed with 285:25 George Yancopoulos, was this one of the 286:01 e-mails? 286:02 A. Yes. This was the e-mail I 286:03 reviewed in preparation for this 286:04 deposition.	00:00:44	KC7.140
D228.1			
287:01 - 287:05	**Chu, Karen 2022-12-16** 287:01 Q. Sure. In your capacity as 287:02 Regeneron's 30(b)(6) witness, what's the 287:03 significance of this April 4th, 2007 287:04 e-mail from George Yancopoulos to Darlene 287:05 Jody?	00:00:12	KC7.141
287:11 - 287:17	**Chu, Karen 2022-12-16**	00:00:27	KC7.142

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DESIGNATION	SOURCE	DURATION	ID
	287:11 A. So this e-mail from George to 287:12 Darlene Jody, who was a senior executive 287:13 responsible for the Bayer collaboration 287:14 with us, is communicating the Regeneron 287:15 proposal and decisions around the optimal 287:16 designs for the VIEW 1 and the VIEW 2 287:17 trials.		KC7.142
289:21 - 290:01	**Chu, Karen 2022-12-16** 289:21 Is there anywhere 289:22 near where Dr. Yancopoulos is 289:23 advocating for starting off the 289:24 regimen with three monthly 2-milligram 289:25 doses, and then going to the 290:01 eight-week interval?"]	00:00:11	KC7.143
290:03 - 290:06	**Chu, Karen 2022-12-16** 290:03 A. In my review of this e-mail, I 290:04 do not see that it includes mention of 290:05 the three initial monthly doses for the 290:06 Q8 week group.	00:00:13	KC7.144
290:13 - 291:02 D229.1	**Chu, Karen 2022-12-16** 290:13 (Defendant's Exhibit 229, 290:14 Document Bates stamped RGN-EYLEA-MYLAN 290:15 00526220 through 223, was so marked 290:16 for identification, as of this date.) 290:17 Q. And did you review this e-mail 290:18 in connection with preparing for your 290:19 deposition in this case? 290:20 A. I have Exhibit 229, dated 290:21 Tuesday, April 10th, 2007, "Subject: 290:22 Forward: VEGF-Trap-Eye GDP for 290:23 REGN/Bayer," from George Yancopoulos to 290:24 Darlene Jody. 290:25 And, no, I did not review this 291:01 e-mail in preparation for today's 291:02 deposition.	00:00:28	KC7.145
293:13 - 293:18	**Chu, Karen 2022-12-16** 293:13 Q. Right. And just to be clear, 293:14 that dosing regimen of VEGF-Trap, 2 293:15 milligrams dosed every four weeks times	00:00:24	KC7.146

DESIGNATION	SOURCE	DURATION	ID
	293:16 three, then Q8 thereafter, that was a 293:17 dosing regimen drafted by Bob Terifay, 293:18 right --		
293:21 - 293:21	**Chu, Karen 2022-12-16** 293:21 Q. -- in this e-mail string?	00:00:01	KC7.147
294:04 - 294:11	**Chu, Karen 2022-12-16** 294:04 A. My recollection of how 294:05 decisions were made at Regeneron at the 294:06 time was that this proposal would not 294:07 have been discussed at the joint 294:08 development committee meeting unless 294:09 George had had input and agreed that this 294:10 was the proposal for the Phase III 294:11 studies.	00:00:22	KC7.148
294:12 - 294:15	**Chu, Karen 2022-12-16** 294:12 Q. Well, if George Yancopoulos had 294:13 signed off on that as the dosing regimen, 294:14 why is he actually arguing against that 294:15 then on April 10th, 2007 to Darlene Jody?	00:00:16	KC7.149
294:20 - 294:24	**Chu, Karen 2022-12-16** 294:20 A. My read of the e-mail didn't 294:21 give me the impression that George was 294:22 arguing against it. If you can point to 294:23 what specifically you're referring to, I 294:24 would be happy to review it again?	00:00:12	KC7.150
295:08 - 295:15	**Chu, Karen 2022-12-16** 295:08 Q. Right. Nowhere in this April 295:09 10th, 2007 e-mail to Darlene Jody is 295:10 George Yancopoulos advocating for the 295:11 dosing regimen that Bob Terifay 295:12 identified as an aflibercept dose of 2 295:13 milligrams dosed every four weeks three 295:14 times, followed by a dosing every 295:15 eight-week regimen, true?	00:00:26	KC7.151
295:19 - 295:23	**Chu, Karen 2022-12-16** 295:19 A. I can't speak to George's 295:20 intent. 295:21 Q. It's not a question of intent. 295:22 It's a question of what's written here in	00:00:08	KC7.152

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DESIGNATION	SOURCE	DURATION	ID
	295:23 the e-mail.		
296:04 - 296:13	**Chu, Karen 2022-12-16**	00:00:24	KC7.153
	296:04 A. It is correct that that is what 296:05 is written in this e-mail is the sentence 296:06 that is based on both U.S. and EU 296:07 regulatory interactions. Such a study 296:08 will definitively fulfill their 296:09 requirements as one of the studies while 296:10 final dose/interval for the fourth arm of 296:11 this study are a bit unsettled, we could 296:12 use 2Q8 for now as the most likely 296:13 dose/interval."		
296:19 - 297:10	**Chu, Karen 2022-12-16**	00:00:49	KC7.154
D230.2	296:19 (Defendant's Exhibit 230, 296:20 Document Bates stamped RGN-EYLEA-MYLAN 296:21 526332 through 334, was so marked for 296:22 identification, as of this date.) 296:23 Q. I would like you to take a look 296:24 at the e-mail from Robert Terifay that is 296:25 dated April 17th, 2007 to George 297:01 Yancopoulos, Len Schleifer, Peter 297:02 Powchik, Avner Ingerman and Neil Stahl, 297:03 "Subject: U.S. Commercial Concerns 297:04 Regarding the Bayer Compromise." 297:05 Let me know when you are there. 297:06 A. I see the e-mail beginning on 297:07 page -- the second page of this e-mail, 297:08 the last three numbers are 333 from 297:09 Robert Terifay, dated 17th of April 2007 297:10 to George Yancopoulos with others copied.		
298:20 - 298:24	**Chu, Karen 2022-12-16**	00:00:09	KC7.155
	298:20 Q. Do you have an understanding as 298:21 to why Robert Terifay would have been 298:22 involved in these discussions over 298:23 selecting the Phase III clinical trial 298:24 regimen?		
299:03 - 299:08	**Chu, Karen 2022-12-16**	00:00:16	KC7.156
	299:03 A. Bob Terifay was the head of our 299:04 commercial group at that time. And as		

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DESIGNATION	SOURCE	DURATION	ID
	299:05 such he would have had input on the 299:06 clinical development program as it 299:07 related to commercial viability and 299:08 commercial considerations.		
306:03 - 306:17	**Chu, Karen 2022-12-16**	00:00:55	KC7.157
	306:03 Q. Again, if we look at DX 230, 306:04 the top e-mail, dated Wednesday, April 306:05 8th, 2007 from Robert Terifay, to Peter 306:06 Powchik, Len Schleifer and George 306:07 Yancopoulos, Avner Ingerman, Neil Stahl 306:08 and Laura Pologe, the second paragraph, 306:09 he says "From an 0508 perspective, it 306:10 appears that 2Q8 (especially if initiated 306:11 as a 2Q4 loading dose for the first three 306:12 months) can offer similar improvement in 306:13 visual acuity and maintain that level 306:14 similarly to 2Q4 and Lucentis Q4. This 306:15 would be a major win for VT," referring 306:16 to aflibercept, "versus Ran," referring 306:17 to ranibizumab "in Phase III," right?		
306:21 - 307:05	**Chu, Karen 2022-12-16**	00:00:28	KC7.158
	306:21 A. I see the e-mail dated 306:22 Wednesday, April 18th, 2007 from Bob 306:23 Terifay to Peter Powchik and others with 306:24 the first bullet stating that "From an 306:25 0508 perspective, it appears that 2Q8 307:01 (especially if initiated as a 2Q4 loading 307:02 dose for the first three months) can 307:03 offer similar improvement in visual 307:04 acuity and maintain that level similarly 307:05 to 2Q4 and Lucentis Q4."		
308:22 - 309:13	**Chu, Karen 2022-12-16**	00:00:58	KC7.159
Clear	308:22 Q. '601 patent, in Claim 1? 308:23 A. So in patent '601, Claim 1, 308:24 it's stated that "A method for treating 308:25 age-related macular degeneration in a 309:01 patient in either comprising intravitally 309:02 administering an effective amount of 309:03 aflibercept, which is 2 milligrams 309:04 approximately every four weeks for the		

DESIGNATION	SOURCE	DURATION	ID
	309:05 first three months, followed by 2 309:06 milligrams approximately once every eight 309:07 weeks or once every two months." 309:08 Q. Right. And that dosing regimen 309:09 matches the one that Robert Terifay is 309:10 advocating for in DX 230, his April 8th, 309:11 2007 e-mail of 2Q8 initiated as a 2Q4 309:12 loading dose for the first three months, 309:13 right?		
309:18 - 309:20	**Chu, Karen 2022-12-16** 309:18 A. My interpretation of the e-mail 309:19 from Bob Terifay is that he is describing 309:20 the same dosing regimen.	00:00:09	KC7.160
310:11 - 311:04	**Chu, Karen 2022-12-16** 310:11 (Defendant's Exhibit 231, 310:12 Document Bates stamped RGN-EYLEA-MYLAN 310:13 528309 through 316, was so marked for 310:14 identification, as of this date.) 310:15 BY MS. MAZZOCHI: 310:16 Q. Ms. Chu, can you confirm that 310:17 this document DX 231 is an e-mail to you 310:18 and others from Avner Ingerman, dated 310:19 Thursday, August 2nd, 2007? 310:20 A. So I have Exhibit 231, which is 310:21 an e-mail dated August 2nd, 2007. The 310:22 subject is "E-Mailing: NCT00509795.HTM" 310:23 from Avner Ingerman, and I am copied on 310:24 this e-mail. 310:25 Q. Okay. And in the text of this 311:01 e-mail, is he providing the information 311:02 that was published at clinicaltrials.gov 311:03 in connection with clinicaltrials.gov 311:04 identifier NCT00509795?	00:00:56	KC7.161
D231.1			
311:05 - 311:09	**Chu, Karen 2022-12-16** 311:05 A. So my review of this e-mail 311:06 this minute indicates that this is 311:07 Dr. Ingerman forwarding the 311:08 clinicaltrials.gov posting of the VIEW 1 311:09 Phase III study.	00:00:22	KC7.162

KC7 - 30(b)(6) Chu Combined Designations

DESIGNATION	SOURCE	DURATION	ID
316:22 - 317:06	**Chu, Karen 2022-12-16**	00:00:33	KC7.163
	316:22 Q. To your prior point, can you 316:23 take a look at the last page of 316:24 Defendant's Exhibit 231? 316:25 Can you confirm above the last 317:01 three lines it says "clinicaltrials.gov 317:02 processed this record on August 1st, 317:03 2007"? 317:04 A. I do see where it says, 317:05 "clinicaltrials.gov processed this record 317:06 on August 1st, 2007."		
318:17 - 318:21	**Chu, Karen 2022-12-16**	00:00:12	KC7.164
Clear	318:17 Q. And under the inclusion 318:18 criteria, the signed informed consent, 318:19 were patients obligated to keep secret 318:20 their participation in Regeneron's 318:21 clinical trials?		
318:24 - 319:01	**Chu, Karen 2022-12-16**	00:00:06	KC7.165
	318:24 A. No. Patients were not 318:25 obligated in any way to keep their 319:01 participation in the study a secret.		
319:15 - 319:18	**Chu, Karen 2022-12-16**	00:00:00	KC7.166
D232.1	319:15 (Defendant's Exhibit 232, 319:16 Document Bates stamped RGN-EYLEA-MYLAN 319:17 526744, was so marked for 319:18 identification, as of this date.)		
319:21 - 320:02	**Chu, Karen 2022-12-16**	00:00:20	KC7.167
	319:21 Q. Do you have it now? 319:22 A. I have Exhibit 232 in front of 319:23 me. 319:24 Q. And are identified as a 319:25 co-author on this presentation? 320:01 A. This appears to be a poster and 320:02 I am listed as an author.		
323:04 - 323:07	**Chu, Karen 2022-12-16**	00:00:11	KC7.168
Clear	323:04 Q. And why did Regeneron want to 323:05 present its data involving aflibercept 323:06 and its clinical trial data at these 323:07 scientific conferences?		

KC7 - 30(b)(6) Chu Combined Designations

DESIGNATION	SOURCE	DURATION	ID
323:11 - 323:16	**Chu, Karen 2022-12-16**	00:00:19	KC7.169
	323:11 A. So it's scientific practice 323:12 that we share our results in the context 323:13 of Scientific Congresses and 323:14 publications. And thus this was part of 323:15 this scientific exchange that we were 323:16 contributing to.		
337:09 - 337:21	**Chu, Karen 2022-12-16**	00:00:37	KC7.170
D232.1	337:09 Could you try to find in your 337:10 stack what they labeled as Defense 337:11 Exhibit 232. 337:12 A. Okay. I have Exhibit 232. 337:13 Q. Ms. Mazzochi, had some 337:14 questions for you about Defense Exhibit 337:15 232. 337:16 Do you know if this is a draft 337:17 or a final document? 337:18 A. I don't know if Exhibit 232 is 337:19 a draft or final.		
Clear	337:20 Q. Okay. You can put that 337:21 document aside.		
340:09 - 340:13	**Chu, Karen 2022-12-16**	00:00:13	KC7.171
D234.1	340:09 Q. On Defendant's Exhibit 234, do 340:10 you have a habit of letting people put 340:11 your name on documents or scientific 340:12 presentations that you don't review and 340:13 approve?		
340:17 - 340:25	**Chu, Karen 2022-12-16**	00:00:17	KC7.172
	340:17 A. No, if I am an author, I 340:18 definitely would have reviewed and 340:19 provided input into the content of the 340:20 document. 340:21 Q. All right. And you would have 340:22 made sure that any statements, at least 340:23 to the extent that they were within your 340:24 area of operation, were truthful and 340:25 accurate, right?		
341:03 - 341:04	**Chu, Karen 2022-12-16**	00:00:04	KC7.173
Clear	341:03 A. Yes, part of my review would be		

KC7 - 30(b)(6) Chu Combined Designations

DESIGNATION	SOURCE	DURATION	ID
	341:04 for accuracy.		
347:09 - 347:12	**Chu, Karen 2022-12-16**	00:00:06	KC7.174
	347:09 Q. And when you were assembling 347:10 that information, that was done with an 347:11 understanding that the data would become 347:12 public, right?		
347:17 - 347:20	**Chu, Karen 2022-12-16**	00:00:10	KC7.175
	347:17 A. Sure. So in assembling data 347:18 for the purpose of a presentation at the 347:19 Scientific Congress, it was understood 347:20 that that data would become public.		

Our Designations	01:02:42
Their Designations	00:12:05
TOTAL RUN TIME	**01:14:48**

Documents linked to video:

D200
D202
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